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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,977	11/20/2001	Benjamin R. Willemstyn		4707

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/01/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,977

Applicant(s)

WILLEMSTYN, BENJAMIN R.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,054,821 to Hillstead et al. Hillstead discloses a connector assembly 11 with a sterile sleeve 14 that covers one end of the connector. The sterile sleeve is attached to the connector by means of an intermediately-located groove 19 which has protrusions, or flanges around each side of the groove that serve to maintain the sleeve in position. The sleeve is otherwise held on the connector by means of an O-ring 16 (See column 4, lines 1-20, FIGS 2-3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,054,821 to Hillstead in view of US 6,039,718 to Niedospial, Jr. et al. Hillstead discloses the apparatus as claimed with the exception of the second

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enclosure bag. Niedospial discloses a universal connector 30 which may be integral with a bag 10 (column 6, lines 55-58) and further comprises an overwrap 210 that serves to make maintain the sterility of the entire device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to cover the connector with the sterile sleeve as disclosed by Hillstead with the overwrap disclosed by Niedospial in order to protect the bag and its contents, as taught by Niedospial.

Furthermore, It would have been an obvious matter of design choice to make the flange or attachment area of the Hillstead device flat or curved, since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. In re Dailey, 149 USPQ 47 (CCPA 1976). Furthermore, applicant fails to disclose any criticality of the shape of the attachment area, and the device appears to function equally well with a straight or curved area for attachment.

5. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,054,821 to Hillstead. It would have been an obvious matter of design choice to make the flange or attachment area of the Hillstead device flat or curved, since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. In re Dailey, 149 USPQ 47 (CCPA 1976). Furthermore, applicant fails to disclose any criticality of the shape of the attachment area, and the device appears to function equally well with a straight or curved area for attachment.

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6. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,054,821 to Hillstead in view of US 5,843,049 to Heilmann et al. Hillstead discloses the apparatus as claimed with the exception that the end of the connector not enclosed by the over-wrap bag is attached to a fluid processing bag. Heilmann discloses an apparatus for administering a medical fluid that includes a connecting conduit tube 31 that has a connector end 34 enclosed in a sealed pouch 20 and a first end 32 heat-sealed in a fluid-filled chamber 25 of a fluid pouch (see column 3, lines 4-26, FIG 1). The device is put together and covered in this manner in order to provide a simple and cost-effective manufactured device that reduces the frequency of infections and prevents microbic contamination of the fluid and connector (see column 1, lines 9-24, 53-65). Therefore, it would have been obvious to provide the connector device with protective sleeve as disclosed by Hillstead with a fluid bag attached to one of the ends of the connector in order to provide a simply manufactured device that protects the sterile nature of the pouch and connector.

While neither Hillstead nor Heilmann disclose that the protective sleeve or overwrap is heat-sealed to the connector, Heilmann discloses that the seals around the outer pouch and the seals between the tubing, fluid pouch, and receptacles are all heat seals that are peelable, in order to be easily detached (see column 2, lines 10-37, column 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the connector and the over-wrap bag with a heat seal to attach them so as to provide a sterile environment for the connector while allowing the over-wrap bag to be easily removed from the connector.

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7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,054,821 to Hillstead in view of US 5,843,049 to Heilmann et al, further in view of US 6,039,718 to Niedospial, Jr. et al. Hillstead and Heilmann disclose the apparatus as claimed with the exception of the second enclosure bag. Niedospial discloses a universal connector 30 which may be integral with a bag 10 (column 6, lines 55-58) and further comprises an overwrap 210 that serves to make maintain the sterility of the entire device. Furthermore, the recitation of a second over-wrap bag amounts to a duplication of the already-recited over-wrap bag of the claimed device. It is generally considered within the capability of one of ordinary skill in the art to duplicate the working parts of a device. See MPEP 2144.04. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to cover the connector with the sterile sleeve as disclosed by Hillstead with the overwrap disclosed by Niedospial in order to protect the bag and its contents, as taught by Niedospial.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,054,821 to Hillstead in view of US 6,039,718 to Niedospial, Jr. et al., further in view of US 5,088,994 to Porat et al. The combined Hillstead and Niedospial device discloses the apparatus as claimed with the exception of the connector comprising a hose barb device. However, Niedospial discloses that his connector is capable of connecting to other devices using means well-known in the art. Porat discloses a bag 1 with a connector spout 11 with a serrated outer surface. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the connector with

serrated or hose-barb edges in order to more securely connect the connector to any desired tubing, as taught by Porat.

9. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,054,821 to Hillstead in view of US 6,183,460 to Smith et al. Hillstead discloses a connector with a sterile wrap, but does not disclose a heat-sealed or zippered connection. It is well-known that sterile wrap bags are sealed in some manner in order to maintain the sterility of the covered device. Smith discloses a chamber 22 with outlet port 34 that connects to some means for transferring fluid to a patient (column 4, lines 42-50). Smith further discloses flaps that provide an overwrap that protects the fluid pouch and connector that may be sealed by a zip strip, weld seal, or a combination of both (column 6, lines 1-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the connector with protective sleeve as disclosed by Hillstead with the zipper closure and zipper-seal combination closure disclosed by Smith in order to provide a disengageable seal, as taught by Smith.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 4,253,500 Williams
 - i. Sterile connector with bag attachments
- b. US 4,925,448 Bazaral
 - ii. Catheter package with overwrap

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c. US 5,932,132 Plemons

iii. Sterile connector apparatus with large fluid chambers

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

lrd 
July 22, 2003



ANGELA D. SYKES
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